REMARKS

Upon entry of the forgoing amendment claims 1, 2, 5-7, 10, 17, 18, 20-24, 26-27, 43, 97, 99-103, 105-106, and 134 will be pending in the application. Claims 1, 5, 27 and 43 are withdrawn from consideration. Claims 98 and 108-133 are cancelled without prejudice. Claims 2 and 97 are amended to require that the pharmaceutical composition consists of 1-methyl-D-tryptophan and pharmaceutically acceptable excipients. Claim 20 has been amended simply to more clearly convey what is claimed. New claim 134 is sought to be added to claim that it is a lung or melanoma tumor that is treatable by the method of the current invention. Support for this amendment can be found, for example, in the specification at page 16, lines 7-9 and current claim 106. No new matter has been introduced by way of these amendments. Entry is respectfully requested.

Rejections under 35 U.S.C. § 102(b)

Claims 2, 98-101, 103, and 105-106 remain rejected under 35 U.S.C. § 102(b) as being anticipated by Van Den Eynde. Applicants respectfully traverse, however in order to advance prosecution, claim 2 has been amended to require that the pharmaceutical composition consists of 1-methyl-D-tryptophan. Van Den Eynde teaches compositions comprising 1-methyl-(D,L)-tryptophan, not pharmaceutical compositions consisting of 1-methyl-D-tryptophan. No where does Van Den Eynde teach or suggest using only the D-isomer of 1 methyl-tryptophan. Withdrawal of this rejection is earnestly solicited.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 2, 98-101, 103, 105-106, 108, 124-127, 129, 131-133 are rejected under 35 U.S.C. § 112, first paragraph as not being enabled for methods of delaying the relapse or

progression of a tumor comprising 1-methyl-D-tryptophan without the use of cyclophosphamide. Applicants respectfully traverse. However, in order to advance prosecution, Applicants have amended the claims to delete the recitation of "delaying the relapse" of a tumor, therefore, the claims now recite a method of delaying the progression of tumor. The data presented in Hou and the Mautino Declaration (both submitted in the response to the previous Office Action) both demonstrate delayed tumor progression in a melanoma and lung cancer model, respectively after administration with 1-methyl-D-tryptophan alone in the absence of further administration of any chemotherapeutic agent. Applicants note that the Examiner has stated that methods of delaying the progression of a melanoma or lung tumor are enabled. The fact that the claimed method has worked in two very different cancers fully enables one skilled in the art to make and use the invention free of undue experimentation. Applicants note, that according to M.P.E.P. § 2164.08, "[a]ll that is necessary is that one skilled in the art be able to practice the claimed invention, given the level of knowledge and skill in the art. Further the scope of enablement must only bear a "reasonable correlation" to the scope of the claims." The Examiner has not shown what type of undue experimentation would be necessary for one of skill in the art to apply the claimed methods to cancers other than melanoma and lung tumors. Applicants respectfully assert that one of ordinary skill in the art would not be unduly burdened by applying the methods of the current invention, which have proven useful in two very different cancers, to any cancer.

Additionally, Applicants respectfully point out to the Examiner, that 1-methyl-D-tryptophan is not necessarily targeting inhibition of IDO within the tumor cell itself, but rather is targeting inhibition of the effects of IDO activity within cells of the hosts immune system, such as IDO^+ dendritic cells (*See* specification at page 21, paragraph beginning at line 21). Therefore, it does not matter whether or not a tumor cell expresses IDO. Therefore, Applicants maintain

that the claims are enabled for methods of delaying the progression of any tumor regardless of IDO expression in that tumor, using pharmaceutical compositions consisting of 1-methyl-D-tryptophan. Notwithstanding the above remarks, Applicants have added new claim 134 directed to a method of delaying the progression of a lung or melanoma tumor by administering a composition consisting of 1-methyl-D-tryptophan. The Examiner has stated in the previous Office Action that a claim directed to these two types of tumors would be fully enabled. Withdrawal is earnestly solicited.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 2, 98-101, 103, 105-106, 108, 124-127, 129 and 131-133 are rejected under 35 U.S.C. § 112, second paragraph for being indefinite with respect to the "consisting essentially of" language. Applicants respectfully disagree, however in order to advance prosecution claim 2 has been amended to recite that the pharmaceutical composition consists of 1-methyl-D-tryptophan. Applicants respectfully submit that the amendments to the claims render this rejection moot. Withdrawal is earnestly solicited.

CONCLUSION

In view of the foregoing, Applicant respectfully submits that no further impediments exist to the allowance of this application and, therefore, requests an indication of allowability. However, the Examiner is requested to call the undersigned if any questions or comments arise.

The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§1.16, 1.17, and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 50-1283.

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Respectfully submitted,
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